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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/159,068	09/23/98	MARATOS-FLIER	E 10276/014002

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EXAMINER

SAQUD, C

ART UNIT	PAPER NUMBER
1647	11

DATE MAILED: 03/20/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.  
09/159,068

Applicant(s)  
MARATOS-FLIER

Examiner  
Christine Saoud

Group Art Unit  
1647



☒ Responsive to communication(s) filed on Jan 31, 2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-46 is/are pending in the application.

Of the above, claim(s) 1-7 and 13-29 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 8-12 and 30-46 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

## DETAILED ACTION

### *Response to Amendment*

1. Claim 8 has been amended and claims 30-46 have been added as requested in the amendment of paper #10, filed 31 January 2001. Claims 1-46 are pending in the instant application.

Applicant should note that new claims were submitted, numbered 13-29. However, claims 13-29 were already pending in the instant application. Therefore, submitted claims 13-29 were renumbered as 30-46 (Rule 1.126).

2. Claims 1-7 and 13-29 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed 31 January 2001 have been fully considered but they are not deemed to be persuasive.

### ***Specification***

6. The attempt to incorporate subject matter into this application by reference to the previously filed application by amendment in paper #9 is improper because it is not in conformance with M.P.E.P. 608.04(b) because the amendment was not part of the original disclosure. Such amendment does not enjoy the status as part of the original disclosure in an application filed under 37 CFR 1.53 unless it is referred to in the oath or declaration filed therewith. Once an oath or declaration is submitted in an application filed under 37 CFR 1.53 identifying the papers which the inventor(s) has "reviewed and understands" as required by 37 CFR 1.63, the original disclosure of the application is defined and cannot be altered merely by filing of a subsequent oath or declaration referring to different papers. If the application is filed without an executed oath or declaration pursuant to 37 CFR 1.53(b), the original oath or declaration submitted later than the filing date must refer to the preliminary amendment filed along with the application in order to comply with 37 CFR 1.63.

The recitation "(and is incorporated by reference in)" should be deleted from the continuing data since it is new matter.

### ***Double Patenting***

7. Applicant is advised that should claims 45 and 46 be found allowable, claims 35 and 30, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim

to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 112***

8. Claims 8-12 and newly submitted claims 30-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record in paper #9 as applied to claims 8-12.

Applicant argues at page 8 of the response that the specification identifies “the structure of peptides useful as MCH antagonists and the identity of critical residues”. This argument is not persuasive because the specification provides conflicting information as to what would constitute an antagonist versus an agonist. Furthermore, the assertion of antagonistic activity is not founded on experimental data, but rather, on salmon MCH activity in teleost skin bioassay and frog and lizard bioassay models. The evidence of record does not establish that these assays and models are effective for predicting MCH mutants which will function as antagonists, absent evidence to the contrary. The instant specification at page 26 states “[i]n preferred embodiments, the antagonist is: MCH(1-16), MCH(2-16), MCH(3-16), MCH(4-16), MCH (5-16)” ..... This contradicts the specification at page 21 which states that MCH(5-15) is sufficient to elicit a response equipotent to native MCH. This is inconsistent in that the specification indicates that the amino acid at position 16 is not required for activity of MCH, but then the specification further states that if it is present, the molecule will be an antagonist. Based on this disclosure, one of

ordinary skill in the art would not know which forms of the modified MCH would act as an antagonist without first making and testing each possible mutant. Although the specification teaches which amino acids are critical for the biological activity of MCH, the disclosure as to which amino acids would be critical for antagonistic activity contradict these statements.

Applicant argues at page 8 of the response that “it would be clear to one skilled in the art that the fragments listed, e.g., MCH(1-16), refer to the corresponding length of the preferred antagonist analogues, and not to fragments of the native peptide, as the Examiner appears to misunderstand”. This argument is not persuasive because it is conventional in the art to denote protein fragments by the protein name and the amino acid structure that is present in the protein fragment (i.e. parathyroid hormone) and then any substitutions or alterations to the native sequence are denoted by indication of the amino acid position and the change that is intended (see for example U.S. Pat. No. 5,229,489 at column 1, lines 30-40). One of ordinary skill in the art at the time the instant invention was made would not interpret MCH(1-16) as being a corresponding length as alleged by Applicant, but rather, a specific molecule embodiment of melanocyte concentrating hormone which consists of amino acids 1-16 of the native molecule, contrary to Applicant’s assertion.

The specification suggests modifications which should be made to the native sequence of MCH (see page 24-25 of the specification), however, the specification fails to provide even a working example, and as stated above, the indicated preferred embodiments would appear to be agonists rather than antagonists, absent evidence to the contrary. One may argue screening for bioactivity could be done, however, this is basically a “wish to know” and the standard for an

enabling disclosure is not one of making and testing. Therefore, the specification does not provide clear guidance as to which amino acids (i.e. structural elements) of the native protein are critical to the biological activity of an antagonist and which amino acids should be altered in order to obtain an MCH antagonist. Without this type of guidance, the skilled artisan does not have a reasonable expectation of making and obtaining a protein that would function as an MCH antagonist, therefore, the instant claims are not enabled.

### ***Conclusion***

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 7AM to 3PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556. If this number is out of service, please call the Group receptionist for an alternate number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March 19, 2001

**CHRISTINE J. SAOUD  
PRIMARY EXAMINER**

*Christine J. Saoud*